

REMARKS/ARGUMENTS:

The above-identified application is currently under final rejection. Reconsideration of the above identified application is respectfully requested.

In the Office action dated September 20, 2005, claims 1-5, 7-23, and 30-35 are rejected under 35 U.S.C. 102(a, b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wong et al. or Liu. These claims are further rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4 and 11 of U.S. Patent No. 6,440,420.

In response to the rejections under 35 U.S.C. § 102 and/or 103, Applicants have amended claims 1, 5, 8-10, 12-13, 16-21, and 23; and cancelled claims 2-3, 6-7, 11, 22, and 24-35. No new matter has been introduced.

Applicants respectfully submit that the amendments of claims and the filing of the terminal disclaimer have overcome the rejections for the reasons set forth below.

Election/Restrictions

In review of the final rejections, claims 24-29 are cancelled. Applicants reserve their rights to file any divisional application(s) to reclaim these claims.

Claim rejection under 35 U.S.C. §102(a)/(b)

Claims 1-5, 7-23 and 30-35 are rejected under 35 U.S.C. § 102(a,b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Wong or Liu.

In response to the rejections, Applicants have amended claims 1, 5, 8-10, 12-13, 16-21, and 23; and cancelled claims 3, 6-7, 11, 22, and 24-35. Applicants respectfully submit that the amendments have complied with the rules under 37 CFR § 1.116.

After the amendments, the present application includes two independent claims, which are claims 1 and 23. The amended claim 1 now claims “a skin cosmetic”, which is a limitation originated from claim 22. The amended claim 1 also clarify that the claim is for a composition, as opposed to only the “oleaginous substances,” and that the oleaginous substances are from germination-activated sporoderm-broken *Ganoderma* spores, by adding the limitations of “a carrier” from claims 3 and the limitation of “germination activation” from claim 2 to the claim. Claims 2-3, and 22 are therefore cancelled. After the amendment, claims 4-5, 8-10, and 16-21 become dependent claims of claim 1.

The amended claim 23 is amended to become an independent claim, which incorporates all of the limitations of the original claims 1, and 2-3 in addition to its own limitation of “a topical formulation having dermatological effort on skin.” As a result of the amendments, claims 12-21 are now dependent claims of the amended claim 23.

The amended claim 1 has the following claim limitations:

- (1) the external preparation contains an oleaginous substances from sporoderm-broken spores of *Ganoderma lucidum* and a carrier;
- (2) the external preparation is a skin cosmetic which applies to external skin of a human;
- (3) the oleaginous substances are extracted from the sporoderm-broken spores of *Ganoderma lucidum* by an SCF-CO₂ method; and
- (4) the skin cosmetic is capable of smoothening the external skin of the human.

Additionally, claims 16-17 further claim a co-application of the external skin preparation and the orally uptake of the oleaginous substances (*i.e.*, claim 16) or the germination-activated sporoderm-broken *Ganoderma* spores (*i.e.*, claim 17), respectively.

The amended claim 23 has the following claim limitations:

- (1) the external preparation contains an oleaginous substances from sporoderm-broken spores of *Ganoderma lucidum* and a carrier;
- (2) the external preparation is a topical formulation having dermatological effect on external skin and is applies to external skin of a human;
- (3) the oleaginous substances are extracted from the sporoderm-broken spores of *Ganoderma lucidum* by an SCF-CO₂ method; and
- (4) the topical formulation is capable of reducing inflammation of the external skin of the human.

Additionally, claims 16-17 further claim a co-application of the external skin preparation and the orally uptake of the oleaginous substances (*i.e.*, claim 16) or the germination-activated sporoderm-broken *Ganoderma* spores (*i.e.*, claim 17), respectively.

To anticipate a claim, each and every element of the claim must be taught, either expressly or inherently, in a single prior art reference. See e.g., *Verdegaal Bros. v. union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (“a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”).

Wong, as previously argued, (*See* argument in the response filed on June 29, 2005, which is incorporated herein by reference), discloses processes for obtaining from *Ganoderma lucidum* the pharmaceutically active fractions which have optical absorbance at about 200-280 nm and

preparations containing the fractions. Wong fails to teach that the Ganoderma is germination-activated Ganoderma lucidum spores. Wong also fails to teach that the external preparation is for a skin cosmetic and that the skin cosmetic has the capability of smoothening the external skin of the human. Wong also fails to teach that the external preparation is for a topical formulation and that the topical formulation has the capability of reducing inflammation of the external skin of the human.

Additionally, nowhere in Wong that the teaching of co-application of the oleaginous substance orally or the germination-activated sporoderma broken Ganoderma spores orally, as shown in claims 16-17, with the external preparation, can be found.

Thus, Wong does not anticipate the claimed invention either expressly or inherently.

Liu discloses a method for extracting oleaginous substances from sporoderm-broken Ganoderma spores. However, contrary to the Examiner's allegation, Liu does not disclose a skin cosmetic (*i.e.*, claim 1) or a topical formulation having dermatological effect on human skin (*i.e.*, claim 23). In addition, nowhere in Liu that the teaching of co-application of the oleaginous substance orally or the germination-activated sporoderma broken Ganoderma spores orally, as shown in claims 16-17, with the external preparation, can be found. Thus, Liu also does not anticipate claim 1 or its dependent claims.

Claim rejection under 35 U.S.C. §103(a)

Claims 1-5, 7-23, and 30-35 are alternatively rejected as being obvious over Wong or Liu.

Applicants respectfully traverse the rejections.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP §706.02(j). Also the teaching or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Aforementioned reasons are further incorporated herein by reference. Neither Liu nor Wong teaches a skin cosmetic that is capable of smoothening the external skin of the human. Additionally, neither Liu nor Wong teaches a topical formulation that is capable of reducing inflammation of the external skin of the human. Thus, claims 1 and 23 and their respective dependent claims are not obvious over Liu and Wong. Furthermore, the combined teachings of Liu and Wong fail to teach or suggest a co-application of the oleaginous substances orally or the germination-activated sporoderma broken Ganoderma spores orally, as shown in claims 16-17, with the external preparation. Thus, claims 16-17 are also not obvious over Liu and Wong.

Double Patenting

Claims 1-5, 7-23 and 30-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 11 of U.S. Patent No. 6,440,420 (hereinafter "Liu").

As a preliminary matter, Since claims 7, 11, 22, and 30-35 are cancelled, so that the issues of double patenting on these claims are moot.

"A double patenting rejection of the obviousness type is 'analogous to [a failure to meet the nonobviousness requirement of 35 U.S.C. 103] except that the patent principally underlying

the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594 (CCPA 1967).

The present invention claims either a skin cosmetic capable of smoothening the external skin (*i.e.*, claims 1-5 and 8-10), or a topical formulation capable of reducing inflammation of the external skin (*i.e.*, claims 12-15, 18-21, and 23). Additionally, claims 16-17 claim a co-application of the oleaginous substances orally or the germination-activated sporoderma broken *Ganoderma* spores orally with the external preparation. The external preparation contains the oleaginous substances from the germination-activated sporoderma broken *Ganoderma* spores and a carrier, which is a composition.

Claims 1-4 and 11 of Liu claim a method for extracting oleaginous substances from spores of *Ganoderma lucidum*.

Nothing in claims 1-4 and 11 of Liu teaches or suggests that the oleaginous substances can be used in a composition to apply to the skin as either a skin cosmetic or a topical formulation, that the skin cosmetic has the capability of smoothening the skin, and that the topical formulation has the capability of reducing inflammation of the skin.

Nothing in claims 1-5, 8-10, 12-16, 19-21, and 23 teaches or suggests a method of making the oleaginous substances from the spores of *Ganoderma lucidum*.

Therefore, the two sets of claims are patentably distinct and there can be no double patenting rejections. Applicants therefore respectfully request that the double patenting rejections be withdrawn.

In view of the foregoing, the objection and rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

Date: January 6, 2006



Fei-Fei Chao, Ph.D. (Reg. No. 43,538)
Bingham McCutchen LLP
Three Embarcadero Center, Suite 1800
San Francisco, California 94111-4067
Tel.: (202) 778-3179
Fax: (202)-778-6155